

Administration between 2-13-51 and 2-8-54, at which times the defendants were informed of certain inadequacies in their control system for the manufacture of the articles, namely, the failure to assay the raw materials used; the lack of care in identifying containers of raw materials, batches of the articles during processing, and the finished articles; the lack of an adequate checking system to insure that the proper amounts of the various chemicals were put into the batches of the chemicals being processed; and the practice of making very few assays of the finished articles. The defendants were warned that such inadequacies would result in errors of composition and labeling with respect to the articles manufactured, and that such inadequacies would result also in the articles being adulterated and misbranded as aforesaid. The defendants had been warned also by 4 seizures and by a notice of hearing. Despite such warnings, the defendants continued to introduce and deliver for introduction into interstate commerce drugs which were adulterated and misbranded as described above.

The complaint alleged also that certain vitamin preparations were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 23244.

DISPOSITION: On 4-29-54, the court entered a temporary restraining order under which the defendants were temporarily restrained from commission of the acts complained of. Thereafter, with the consent of the parties, the temporary restraining order was continued in effect pending the final determination of the matter.

On 12-12-55, a consent decree of permanent injunction was entered against Bonded Laboratories, Inc., its agents, servants, employees, and representatives, and all and any persons in active concert or participation with them, and against the president of Bonded Laboratories, Inc., whether in connection with such corporation or independently, enjoining them against introducing or delivering for introduction into interstate commerce any foods and drugs which are adulterated and misbranded as charged in the complaint, and which are manufactured, prepared, and packed by Bonded Laboratories, Inc., without the utilization of good controls necessary to the end that an article of proper composition is purchased and shipped.

5066. Aspirin tablets. (F. D. C. No. 35661. S. No. 52-623 L.)

QUANTITY: 2 50,000-tablet drums at Greystone Park, N. J.

SHIPPED: 7-14-53, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LABELED: 9-25-53, Dist. N. J.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, "Aspirin Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its quality and purity fell below the standard set forth in such compendium in that the article had a strong odor of acetic acid, many of the tablets were discolored, and a portion of the tablets contained less than 5 grains of acetylsalicylic acid.

DISPOSITION: 10-30-53. Default—destruction.

5067. Sulfadiazine tablets and diethylstilbestrol tablets. (F. D. C. No. 36103. S. Nos. 50-555 L, 50-557 L.)

QUANTITY: 17 100-tablet btls. of *sulfadiazine tablets* and 33 100-tablet btls. of *diethylstilbestrol tablets* at Newark, N. J.

SHIPPED: 7-2-53, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Tablets List 525 Quality R/W Products Sulfadiazine (2-Sulfanilamidopyrimidine) 7.7 Grains (0.5 Gm.)" and "100 Tablets List 340 Diethylstilbestrol 5 Mg."

RESULTS OF INVESTIGATION: Analyses showed that the *sulfadiazine tablets* contained not more than 78.3 percent of the labeled amount of sulfadiazine and that the *diethylstilbestrol tablets* contained not more than 76.4 percent of the labeled amount of diethylstilbestrol.

LIBELED: 11-9-53, Dist. N. J.

CHARGE: *Sulfadiazine tablets*. 501 (b)—the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its strength differed from, and its quality fell below, the official standard since the article contained less than 95 percent of the labeled amount of sulfadiazine, the minimum permitted by the standard, and the article failed to meet the test for individual weight variation for tablets as prescribed in the standard.

Diethylstilbestrol tablets. 501 (b)—the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its strength differed from the official standard since the article contained less than 90 percent of the labeled amount of diethylstilbestrol, the minimum permitted by the standard.

DISPOSITION: 12-16-53. Default—destruction.

5068. Clinical thermometers. (F. D. C. No. 38960. S. Nos. 1-849 M, 1-875/6 M.)

QUANTITY: 195 *clinical thermometers* at Wilmington, N. C.

SHIPPED: 12-22-55, from New York, N. Y., by Affiliated Drug Stores, Inc.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind—Rectal [or "Oral"]."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Accuracy For Clinical Thermometer * * * Cardinal Thermometer Co. 67-02 60th Street Brooklyn 27, N. Y."

RESULTS OF INVESTIGATION: Examination revealed that 7 out of 48 thermometers taken from this lot failed to comply with Commercial Standard CS1-52 since 5 failed to give readings of required accuracy and 2 failed to meet the hard shaker test.

LIBELED: 2-20-56, E. Dist. N. C.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article, when shipped, namely, "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1-52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce," was false and misleading.

DISPOSITION: 4-11-56. Default—destruction.

5069. Clinical thermometers. (F. D. C. No. 38987. S. No. 48-371 M.)

QUANTITY: 121 *clinical thermometers* at Passaic, N. J.

SHIPPED: 12-12-55, from New York, N. Y., by Emrose Thermometer Co.